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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,884	10/23/2000	Kiyozo Asada	1422-443P	6983

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EXAMINER

STRZELECKA, TERESA E

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 02/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/673,884		ASADA ET AL	
	Examiner		Art Unit	
	Teresa E. Strzelecka		1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2005 and 13 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16,18,21-23,31,32,34 and 36-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16,18,21-23,31,32,34 and 36-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on October 13, 2005 and December 13, 2005 has been entered.

2. Claims 16, 18, 21-23 and 31-35 were previously pending. Applicants amended claims 16, 18 and 22, cancelled claims 33 and 35 and added new claims 36-38. Claims 16, 18, 21-23, 31, 32, 34 and 36-38 are pending and will be examined.

3. Applicants' amendments overcame the following rejections: rejection of claim 16 under 35 U.S.C. 102(b) as anticipated by Demeke et al.; rejection of claim 16 under 35 U.S.C. 102(b) as anticipated by Tasa et al.; rejection of claims 22, 23 and 35 under 35 U.S.C. 102(e) as anticipated by Koster et al.; rejection of claims 18 and 21 under 35 U.S.C. 103(a) over Demeke et al. and Barnes; rejection of claims 31-34 under 35 U.S.C. 103(a) over Demeke et al., Barnes and Stratagene Catalog; rejection of claims 18 and 21 under 35 U.S.C. 103(a) over Tasa et al. and Barnes; rejection of claims 31-34 under 35 U.S.C. 103(a) over Tasa et al., Barnes and Stratagene Catalog. All other rejections are maintained for reasons given in the "Response to Arguments" section below. This action contains new grounds for rejection necessitated by amendment.

Response to Arguments

4. Applicant's arguments filed October 13, 2005 have been fully considered but they are not persuasive.

A) Regarding the rejection of claim 16 under 35 U.S.C. 102(b) as anticipated by Leob et al., Applicants argue that the metal compounds of Leob et al. are metal salts, not metal complexes, comprising at least one atom of transition metal element and at least one ligand.

However, Applicants did not define the term "transition metal complex", therefore, as explained in the previous office action, this term is interpreted as any transition metal compound. Further, Applicants' own disclosure seems to support the examiner's interpretation of this term (page 10, lines 4-22 of the specification):

"The transition metal complex may be any complex capable of exhibiting an action of enhancing DNA synthesis reaction, and complexes having as the central atom a transition element in Group VIII of the Periodic Table (Kagaku Jiten, 1st edition, Tokyo Kagaku Dojin) are preferred. The above Group VIII transition element includes, but not particularly limited, as long as it forms a complex capable of exhibiting an action of enhancing DNA synthesis reaction, for instance, cobalt (Co), rhodium (Rh), iridium (Ir) and the like. In addition, the ligands in the complex include, but not particularly limited to, monodentate ligands, bidentate ligands, tridentate ligands, and tekadentate ligands. For example, neutral ligands such as H_2O , NH_3 , CO , NO and pyridine, and chelate ligands such as $\text{H}_2\text{NCH}_2\text{CH}_2\text{NH}_2$ may be exemplified. In addition, the complex may contain as a ligand an anionic ligand, for instance, Cl^- , OH^- , NO_2^- , CN^- , Co_2^- or the like, as long as it is a cationic complex capable of being present as a complex cation in the reaction mixture. The kinds of ligands in the above complex may be one kind or a plural kinds. Furthermore, as to cationic complexes, there exist geometric isomers, optical isomers and linkage isomers, and any cationic complexes are included in the DNA synthesis reaction-enhancer of the present invention, as long as they have an action of enhancing DNA synthesis reaction."

Therefore, according to Applicants' own description of transition metal complexes, transition metal salts qualify as such.

The rejection is maintained.

B) Regarding the rejection of claim 16 under 35 U.S.C. 102(b) as anticipated by Diringer et al., Applicants argue that Diringer et al. teach reverse transcriptase and chondroitin sulfate, dextran and heparin, which limitations are not present in the amended claims. However, Diringer et al. also teach polyvinyl sulfates, therefore the rejection is maintained.

Claim Interpretation

5. The term "DNA-synthesis reaction-enhancer" in claim 16, 18, 31 and 36 does not refer to a structural feature of any of the compound listed in these claims, therefore it is not considered when the claimed subject matter is compared with prior art.

6. The phrase "transition metal complex" has not been defined by Applicants, therefore any compound comprising a transition metal is considered to anticipate this term.

7. The phrases " α -type polymerase" and "non- α , non-pol I type DNA polymerase" have not been defined by Applicants, therefore any polymerase is considered to anticipate these terms.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Loeb et al. (U.S. Patent No. 4,072,574; cited in the previous office action).

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Loeb et al. teach a DNA synthesis reaction composition comprising an AMV DNA polymerase and one of the following transition metal complexes of silver, cobalt, chromium, copper, iron, manganese and nickel together with reaction components necessary for DNA synthesis (col. 4, lines 44-60; Table 1). Therefore, Loeb et al. anticipate the limitations of claim 16.

10. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Diringier et al. (U.S. Patent No. 5,153,181; cited in the previous office action).

Diringier et al. teach a DNA synthesis composition comprising SR-D reverse transcriptase (= DNA polymerase) and one of the following compounds: polyvinyl sulfates, polyvinyl phosphates and polymeric carbohydrates together with reaction components necessary for DNA synthesis (col. 3, lines 14-16; col. 4, lines 23-39). Therefore, Diringier et al. anticipate the limitations of claim 16.

11. Claims 16, 31, 32 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Filler et al. (U.S. Patent No. 5,554,498 A).

Regarding claim 16, Filler et al. teach a DNA synthesis reaction composition comprising a DNA polymerase and transition metal complexes of scandium, yttrium, copper, nickel, zinc, cobalt, manganese, palladium and ruthenium together with components necessary for DNA synthesis (col. 9, lines 1-36; col. 10, lines 36-56; col. 11, lines 46-67; col. 12, lines 1-36; Tables 1, 2, 4, 5, 7, 8). The metal ion solutions contain Cl^- as ligands (col. 11, lines 59-62).

Regarding claims 31 and 32, Filler et al. teach a kit for DNA synthesis comprising transition metal ion salts, DNA polymerase or reverse transcriptase (RNA-dependent DNA polymerase), a template and buffer solution (col. 19, lines 20-32; col. 20, lines 1-7).

Regarding claim 34, Filler et al. teach a thermostable DNA polymerase (col. 2, lines 43-48).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 18, 21, 23 and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sorge et al. (U.S. Patent No. 5,556,772 A) and Filler et al. (U. S. Patent No. 5,554,498 A).

A) Regarding claims 18, 21 and 23, Sorge et al. teach a DNA synthesis reaction composition comprising two different DNA polymerases, one with 3'-5' exonuclease activity and one without such activity, and components necessary for the DNA synthesis (Abstract; col. 2, lines 7-16; col. 5, lines 30-67; col. 6, lines 1-17; col. 11, lines 58-67; Table 17).

Regarding claims 36 and 37, Sorge et al. teach kits comprising two DNA polymerases and reagents for amplification (col. 5, lines 7-19; col. 45, lines 59-67; col. 46, lines 58-63).

Regarding claim 38, Sorge et al. teach thermostable DNA polymerases (col. 5, lines 30-67; col. 6, lines 1-17; col. 46, lines 64,65).

B) Sorge et al. teach magnesium salts in the reaction mixture, but do not teach transition metal ion complexes.

C) Regarding claim 18, Filler et al. teach a DNA synthesis reaction composition comprising a DNA polymerase and transition metal complexes of scandium, yttrium, copper, nickel, zinc, cobalt, manganese, palladium and ruthenium together with components necessary for DNA synthesis (col. 9, lines 1-36; col. 10, lines 36-56; col. 11, lines 46-67; col. 12, lines 1-36; Tables 1, 2, 4, 5, 7, 8). The metal ion solutions contain Cl⁻ as ligands (col. 11, lines 59-62).

Regarding claims 36 and 37, Filler et al. teach a kit for DNA synthesis comprising transition metal ion salts, DNA polymerase or reverse transcriptase (RNA-dependent DNA polymerase), a template and buffer solution (col. 19, lines 20-32; col. 20, lines 1-7).

Regarding claim 38, Filler et al. teach a thermostable DNA polymerase (col. 2, lines 43-48).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used transition metal complexes of Filler et al. in the DNA synthesis composition of Sorge et al. The motivation to do so, provided by Filler et al., would have been that using the transition metal ions increased rate and processivity of DNA polymerases (col. 2, lines 9-21; col. 3, lines 1-10; col. 5, lines 30-42), resulted in production of longer transcripts and allowed adjustment of amplification conditions (col. 3, lines 11-18), and inhibited nucleases present in reaction mixtures (col. 2, lines 22-35; col. 3, lines 41-49; col. 5, lines 53-64).

14. Claims 18 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koster et al. (U.S. Patent No. 5,928,906 A; cited in the previous office action) and Filler et al. (U. S. Patent No. 5,554,498 A).

A) Regarding claims 18 and 22, Koster et al. teach the composition comprising two or more kinds of DNA polymerase having 3'-5' exonuclease activity that is not reduced relative to wild-type and Mg^{2+} (col. 7, lines 43-67; col. 8, lines 1-12; col. 12, lines 19-37).

B) Koster et al. teach magnesium salts in the reaction mixture, but do not teach transition metal ion complexes.

C) Regarding claims 18 and 22, Filler et al. teach a DNA synthesis reaction composition comprising a DNA polymerase and transition metal complexes of scandium, yttrium, copper, nickel, zinc, cobalt, manganese, palladium and ruthenium together with components necessary for

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DNA synthesis (col. 9, lines 1-36; col. 10, lines 36-56; col. 11, lines 46-67; col. 12, lines 1-36; Tables 1, 2, 4, 5, 7, 8). The metal ion solutions contain Cl^- as ligands (col. 11, lines 59-62).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used transition metal complexes of Filler et al. in the DNA synthesis composition of Koster et al. The motivation to do so, provided by Filler et al., would have been that using the transition metal ions increased rate and processivity of DNA polymerases (col. 2, lines 9-21; col. 3, lines 1-10; col. 5, lines 30-42), resulted in production of longer transcripts and allowed adjustment of amplification conditions (col. 3, lines 11-18), and inhibited nucleases present in reaction mixtures (col. 2, lines 22-35; col. 3, lines 41-49; col. 5, lines 53-64).

15. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TERESA STRZELECKA
PATENT EXAMINER
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2/17/06